REMARKS

The Examiner states that Claims 48 and 49 are in a condition for allowance over the prior art but must still overcome the double-patenting rejection. However, as explained below, the double-patenting rejection is in error. Therefore, it is respectfully requested that these claims be allowed.

Applicants will address each of the Examiner's rejections in the order in which they appear in the Final Rejection of June 6, 2005.

Claim Rejections - 35 USC §102

In the Office Action, the Examiner rejects Claims 29-35, 37, 42-44 and 47 under 35 USC §102(e) as being anticipated by Saab et al. (US publication 2005/0113893). This rejection is respectfully traversed.

The present application is directed to a catheter for the delivery of radiation treating elements to a selected location within the intraluminal passageways for treatment using such treating elements. As explained in the specification (e.g. page 26, ln. 29 - page 28, ln. 13) and shown in the drawings (see e.g. Figs. 7A and 7B) of the present application, the catheter has one tube for a guidewire and another tube (treating element tube) sized to slidingly receive the treating element(s) for advancing the treating element through the tube from the proximal end of the tube (at the proximal end of the catheter) to the distal end of the tube (at the distal end of the catheter), to prevent the treating element from exiting the first lumen to outside the catheter at the distal end of the catheter, and for return of the treating elements through the tube to the proximal end of the tube and out of the patient. A return lumen is provided between the space between the inner surface of an outer tube and the outer surfaces of the guidewire tube and the treating element tube. The return lumen is provided for return of fluid used for moving the treating elements from the proximal end to the distal end of treating

element tube but the treating elements do not flow into the return lumen. After sufficient irradiation has occurred at the treatment site, the flow of fluid is reversed through the return fluid lumen and the treating elements move from the distal end to the proximal end of the treating element tube. By having only one tube for advancing the treating elements from the proximal end of the catheter to the treatment site at the distal end of the catheter and retrieval of the treating elements, the amount of radiation given to the patient, where the radiation treatment occurs and the length of exposure of the radiation to the treatment site (i.e. the selected location) can be controlled.

In contrast to the catheter of the present application, Saab is directed to a heat transfer catheter. With such a catheter, a major concern is that the heat transfer fluid (which is at a different temperature than body temperature, either colder or hotter) will quickly approach body temperature at locations distal to the proximal point of the catheter where the fluid is introduced. As a result, any temperature difference, even at the proximal end, exists for only a relatively short time until the fluid at every point along the catheter is heated or cooled to body temperature, which would render the attempted treatment with such fluid worthless. See e.g. [0016] in Saab. Therefore, it is desirable to have the heat transfer fluid reach the treatment area as quickly as possible before the fluid heats/cools to body temperature and to provide a continuous flow of such fluid.

Accordingly, Saab discloses a closed loop fluid containment system and circulation system whereby hear transfer fluid from a first inlet lumen is passed directly to a second outlet lumen to form a continuous flow of heat transfer fluid. [0031; Fig. 1.] This arrangement in Saab is considered advantageous for introducing fluids at different temperatures. However, the fluid in Saab is only able to flow in a single direction, i.e. from the inlet lumen to the return lumen. The Saab device is not created to have fluid communication in two directions so as to enable reverse fluid flow to remove treating elements from the body.

Further, there is no disclosure or suggestion in Saab of treating elements or of a treating element lumen wherein treating elements flow from the proximal end to the distal end of the treating element lumen and then are able to stay at the distal end of the treating element lumen (and the desired treatment area) for as long as necessary. Thereafter, the treating elements are returned back through the treating element lumen to the proximal end of the lumen and out of the patient. If such treating elements were used in the Saab device, they would quickly flow by desired treatment area (at the distal end of the catheter) and pass back to the proximal end of the catheter through the fluid return lumen and would be in the treatment area for only a fraction of a second. This does not allow sufficient time for treatment nor does it allow for control of the treatment or treatment time. Hence, the device in Saab is very different and works in a very different manner than the catheter of the present application.

In order to make this distinction clear, Applicants are amending independent Claims 29 and 44 to recite "wherein said at least one treating element is movable through said first elongated tube from a proximal end of said first elongated tube to a distal end of said first elongated tube for treatment of the selected site in the body and movable back through said first elongated tube to said proximal end of said first elongated tube." This feature is clearly not disclosed or suggested by Saab.

It is further noted that dependent Claim 33 requires the first elongated tube to have an internal barrier to block the passage of treating elements out of the first tube. Saab clearly does not disclose or suggest this feature as any treating element in Saab would flow right out of the first tube into the second tube.

Therefore, since Saab fails to disclose or suggest the catheter of independent Claims 29 and 44 or those claims dependent thereon, these claims are patentable over Saab. Accordingly, it is respectfully requested that this rejection be withdrawn.

Double Patenting

The Examiner also rejects Claims 29-35, 37, 42-44, 47-49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-32 of copending application no. 10/817,549. This rejection is respectfully traversed.

Claims 29, 30, and 31 of the '549 application were originally filed in the present application as Claims 41, 45, 46, respectively (see Amendment C filed September 11, 2003). The Examiner of the present application, however, stated that "Newly submitted claims 41, 45 and 46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a non-elected species. . . Accordingly, claims 41, 45 and 46 are withdrawn from consideration as being directed to a non-elected invention." (see Office Action of December 2, 2003). As a result of that holding, Applicants filed the '549 application.

As the Examiner of the '549 application is the same as the Examiner of the present application, it is respectfully submitted that this rejection is erroneous. Further, in light of the Examiner's original position that there is a separate invention in these claims, the Examiner is estopped from making this double patenting rejection. Accordingly, it is respectfully requested that the rejection be withdrawn.

Conclusion

Therefore, the present application is in an allowable condition and should be allowed.

If any further fee is due for this amendment, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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